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(11) EP 0 646 351 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: 10.02.1999 Bulletin 1999/06

(51) Int. Cl.6: A61B 17/00

(21) Application number: 94306428.7

(22) Date of filing: 01.09.1994

(54) Surgical mesh applicator

Applikator für blattförmiges chirurgisches Material Applicateur pour la matière chirurgicale en feuille

(84) Designated Contracting States: **DE FR GB**

(30) Priority: 02.09.1993 US 116160

(43) Date of publication of application: 05.04.1995 Bulletin 1995/14

(73) Proprietor: ETHICON, INC. Somerville, NJ 08876 (US)

(72) Inventors:

Kammerer, Gene W.
 East Brunswick, NJ 08816 (US)

Tolkoff, Joshua M.
 Brookline, Massachusetts 02146 (US)

Allman, Robert C.
 Wakefield, Massachusetts 01880 (US)

Muise, George R.
 Stow, Massachusetts 01775 (US)

(74) Representative:
Fisher, Adrian John et al
CARPMAELS & RANSFORD
43 Bloomsbury Square
London WC1A 2RA (GB)

(56) References cited:

EP-A- 0 525 791 EP-A- 0 544 485

EP-A- 0 543 499

EP-A- 0 557 963

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to an applicator adapted for applying a sheet of surgical material such as a surgical mesh to tissue within a human body and, more particularly, to a surgical mesh applicator including an expandable spreader tip which is insertable into the body through an incision to enable a surgeon to apply a surgical mesh to tissue inside the body. The applicator is particularly suitable for insertion through an endoscopic tube for spreading a surgical mesh over internal body tissue in the performance of surgery to repair a hernia.

BACKGROUND OF THE INVENTION AND PRIOR ART

[0002] In the prior art, it is known to utilize an inserter device for the purpose of installing an absorbant tampon in the internal vaginal cavity. For example, U. S. Patent 3,857,395 discloses an inserter device which includes a pair of outwardly bendable arms which bilaterally spread the tampon within the vaginal cavity.

[0003] In addition, other types of instruments are known in the prior art for manipulating internal body tissue. For example, U. S. Patent 4,909,789 discloses observation assisting forceps including a set of expandable wires mounted on a shaft which is normally retracted into a sheath. When the shaft is advanced, the wires project out of the sheath and expand into a fanshaped configuration in the same plane. The expanded wires can be used to set aside internal organs obstructing the observation with an abdominal cavity endoscope. The wires are provided at the tips with spherical members which prevent the organs from being hurt.

U. S. Patent 4,654,028 discloses an incision opening expansion holder including a plurality of wires at the end of an inner tube which are three dimensionally expanded when projecting out of an outer tube to expand an incision of a blood vessel graft for purposes of inosculation. U. S. Patent 4,705,041 discloses a tissue dilator comprising a catheter which supports an expandable member, e.g., a balloon or a scissor-like member. U. S. Patent 1,878,671 discloses a dilator for opening a body cavity including an ovate head mounted on a wire received in a tube which is inserted into the body cavity. U. S. Patent 4,655,219 discloses a tissue grasping accessory including a plurality of flexible grasping arms for use with an endoscopic instrument to grasp a tissue specimen. U. S. Patent 4,590,938 discloses a device for removal of kidney stones through the working channel of an endoscope including a basket comprising four outwardly bowed, generally flat spring arms which are expandable into a bulbous shape and collapsed when retracted into a sheath. The relatively broad, flat surfaces of the spring strips deflect the kidney tissue surrounding the stone while the distally enlarged volume of the basket allows the surgeon to dislodge and capture the stone.

[0005] EP-A-543499, upon the disclosure of which the two-part form of claim 1 is based, discloses an applicator for applying a sheet of surgical material, e.g., an absorbable adhesion barrier, to internal body tissue to reduce the incidence of post-operative adhesions. The applicator is insertable into a trocar or endoscopic tube through an incision in a body wall to enable a surgeon to apply the adhesion barrier to tissue inside the body. The applicator includes a set of telescoping tubes comprising an outer delivery tube, an intermediate deployment tube, and an inner irrigation tube. An expandable spreader tip is mounted at the distal end of the irrigation tube and connected to the distal end of the deployment tube. By advancing the deployment tube and irrigation tube relative to the delivery tube, the expandable spreader tip is exposed at the distal end of the delivery tube. The spreader tip is expanded by movement of the deployment tube relative to the irrigation tube to spread the adhesion barrier over the tissue. A nozzle is provided at the distal end of the irrigation tube for applying a saline solution to the adhesion barrier.

[0006] The adhesion barrier applicator of EP-A-543499 is advantageously employed in performing gynecologic-pelvic surgery to apply an adhesion barrier to internal body tissue. The adhesion barrier is applied at the surgical site to the traumatized tissue surfaces after hemostasis to physically separate opposing tissue surfaces during the period of repair or reperitonealization of the tissue. The adhesion barrier applicator is particularly suitable for applying an adhesion barrier of relatively small size to the internal body tissue. The adhesion barrier applicator employs a single stroke actuator mechanism to expose the spreader tip at the distal end of the delivery tube and expand the spreader tip to spread the adhesion barrier over the tissue. During the one-stroke operation of the acutator mechanism, the spreader tip cannot be repositioned on the tissue until the expansion of the spreader tip is completed. Thus, prior to the actuation of the adhesion barrier applicator, the spreader tip must be accurately aligned with the surgical site. Once the operation of the actuator mechanism is initiated, it is difficult to adjust the position of the spreader tip on the tissue. Also, the spreader tip of the adhesion barrier applicator does not incorporate any grasping features to enhance the ability of the spreader tip to adjust the position of the adhesion barrier on the tissue. Further, in the operation of the adhesion barrier applicator, the deployment tube cannot be rotated about its axis relative to the delivery tube to adjust the angular orientation of the spreader tip and the adhesion barrier.

[0007] Accordingly, it is an object of the present invention to provide an applicator which is adapted to precisely control the placement of a sheet of surgical material such as a surgical mesh to internal body tissue.

[0008] Another object of the invention is to provide an applicator to facilitate the installation of a sheet of surgical material such as a surgical mesh through an endoscopic tube to tissue in a body cavity.

[0009] It is also an object of the invention to provide a surgical mesh applicator which is suitable for insertion through an endoscopic tube and is adapted to spread the surgical mesh over a tissue application area to minimize the need for manipulation of the surgical mesh by separate grasping instruments.

[0010] A further object of the invention is to provide a surgical mesh applicator including an expandable spreader tip which is rotatable when retracted into the delivery tube and when exposed from the delivery tube to allow the angular orientation of the surgical mesh to be adjusted.

[0011] It is a further object of the invention to provide a surgical mesh applicator including an expandable spreader tip which is adapted to grip the surgical mesh to facilitate the placement of the surgical mesh in a desired position on the tissue.

SUMMARY OF THE INVENTION

[0012] The present invention achieves an applicator which is adapted for insertion through a trocar or endoscopic tube to apply a sheet of surgical material such as a surgical mesh to internal body tissue. The applicator can also be used to apply other types of fabrics used in surgery, e.g., topical hemostats, adhesion barriers and surgical patches.

[0013] The invention is embodied in an applicator for applying a spreadable sheet of surgical material to internal body tissue comprising a delivery tube, a deployment tube slidably received within the delivery tube, and a shaft slidably received within the deployment tube with a distal end of the shaft projecting from the distal end of the deployment tube. An expandable spreader tip is mounted at the distal end of the shaft and connected to the distal end of the deployment tube for spreading the sheet of surgical material over the tissue. The spreader tip is collapsed when inserted in the delivery tube with the surgical material. The applicator includes means for retracting the delivery tube relative to the deployment tube and the shaft to expose the spreader tip and the surgical material at the distal end of the delivery tube. The applicator includes first actuator means for urging the spreader tip and the surgical material into engagement with the tissue as the deployment tube is retracted and second actuator means for advancing the deployment tube relative to the shaft to expand the spreader tip to apply the surgical material to the tissue. Preferably, a return spring is provided for biasing the deployment tube in the proximal direction relative to the shaft to normally maintain the spreader tip collapsed.

[0014] In accordance with one aspect of the present invention, the spreader tip comprises a plurality of flexible strips each pivotally connected at its opposite ends

to the distal end of the shaft and to the distal end of the deployment tube. The strips are flexed outwardly when the deployment tube is advanced relative to the shaft to spread the surgical material over the tissue. Each of the flexible strips has an intermediate portion which bulges laterally outward when the strip is flexed for spreading the surgical material over the tissue. Preferably, the strips are spaced circumferentially apart about the spreader tip. When the spreader tip is actuated, the strips flex laterally outward into a convex shape to spread the surgical material over the tissue.

[0015] A preferred embodiment of the spreader tip includes a plurality of distally extending prongs for engaging the sheet of surgical material to adjust the placement of the surgical material on the tissue. The prongs function as fabric engaging fingers which allow the sheet of surgical material to be displaced and rotated by movement of the spreader tip over the tissue. [0016] In accordance with another aspect of the invention, the deployment tube and shaft of the applicator are rotatable together relative to the delivery tube to adjust the angular orientation of the spreader tip and the surgical material. Thus, the spreader tip is rotatable when retracted inside the delivery tube and when exposed at the distal end of the delivery tube to facilitate the desired alignment and placement of the surgical material on the tissue.

A preferred embodiment of the applicator [0017] includes latch means for latching the delivery tube in a retracted position with the spreader tip and the surgical material exposed at the distal end of the delivery tube. The latch means is operable in any rotational orientation of the deployment tube relative to the delivery tube to latch the delivery tube in the retracted position. The latch means is adapted to permit rotation of the deployment tube and the shaft relative to the delivery tube with the delivery tube latched in the retracted position. Preferably, the latch means comprises a latching member on the delivery tube and a latch ring on the deployment tube adapted to engage the latching member in any rotational orientation of the deployment tube relative to the delivery tube when the delivery tube is moved to the retracted position. The latching member and latch ring permit the spreader tip to be disposed in any desired angular orientation when it is exposed at the distal end of the delivery tube.

[0018] In accordance with another aspect of the invention, the application includes detent means for releasably engaging the deployment tube to retain the spreader tip inside the delivery tube prior to the exposure of the spreader tip from the distal end of the delivery tube. The detent means is operable in any rotational orientation of the deployment tube relative to the delivery tube to retain the spreader tip inside the delivery tube. The detent means is adapted to permit rotation of the deployment tube and shaft relative to the delivery tube with the spreader tip retracted inside the delivery tube. Preferably, the detent means comprises a latching

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member on the delivery tube and an annular groove on the deployment tube adapted to engage the latching member in any rotational orientation of the deployment tube relative to the delivery tube when the spreader tip is retracted.

[0019] In a preferred embodiment of the applicator, a hollow funnel-shaped flange is provided at the proximal end of the delivery tube for guiding the spreader tip and the surgical material into the delivery tube. The shaft comprises an irrigation tube for supplying fluid, e.g., a saline solution, to the sheet of surgical material. A nozzle is provided at the distal end of the irrigation tube for discharging the fluid therefrom. Preferably, the nozzle includes a plurality of distally extending prongs for engaging the sheet of surgical material to adjust the placement of the surgical material on the tissue.

[0020] In another embodiment of the applicator, a pickup mechanism is provided for securing the sheet of surgical material to the spreader tip. The pickup mechanism comprises a wire slidably mounted on the spreader tip and provided with a hook for engaging the surgical material. The hook is adapted to snare the sheet of surgical material on the spreader tip to allow the sheet to be picked up and maneuvered into a desired position. The hook is located at the distal end of the wire and can be controlled from the proximal end of the applicator so that the hook can be extended from or retracted into the spreader tip.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The foregoing and other objects, aspects and advantages will be better understood from the following detailed description of the preferred embodiments of the invention with reference to the drawings, in which:

Figure 1 is a front perspective view of the first embodiment of a surgical mesh applicator constructed in accordance with this invention;

Figure 2 is a rear perspective view of the surgical mesh applicator of Figure 1;

Figure 3 is a partially cutaway side elevation of the surgical mesh applicator of Figure 1;

Figure 4 is a partially cutaway top view of the surgical mesh applicator of Figure 3;

Figure 5 is a longitudinal section of the surgical mesh applicator of Figure 3;

Figure 6 is a longitudinal section of the surgical mesh applicator of Figure 3 showing the spreader tip exposed;

Figure 7 is a longitudinal section of the surgical mesh applicator of Figure 3 showing the spreader tip expanded;

Figure 8 is a vertical section of the surgical mesh applicator along line 8-8 of Figure 3;

Figure 9 is a vertical section of the surgical mesh applicator along line 9-9 of Figure 3;

Figure 10 is an enlarged, partially cutaway longitu-

dinal section showing the spreader tip and nozzle of the surgical mesh applicator;

Figure 11 is a distal end view of a retainer member and pivot ring at the distal end of the spreader tip;

Figure 12 is a longitudinal section of the retainer member along line 12-12 of Figure 11:

Figure 13 is an end view of the pivot ring of Figure 11:

Figure 14 is a proximal end view of a retainer member and pivot ring at the proximal end of the spreader tip;

Figure 15 is a longitudinal section of the retainer member along line 15-15 of Figure 14;

Figure 16 is an end view of the pivot ring of Figure 14;

Figure 17 is a distal end view of the nozzle at the distal end of the spreader tip;

Figure 18 shows the nozzle of the spreader tip engaged with a surgical mesh;

Figure 19 shows a modified embodiment of the surgical mesh applicator of the present invention:

Figures 20 and 21 illustrate the operation of the modified embodiment of Figure 19:

Figure 22 shows a further embodiment of the surgical mesh applicator of the present invention;

Figure 23 is a partially cutaway side view illustrating the insertion of a surgical mesh into the applicator of Figure 3;

Figures 24-26 are fragmentary views which illustrate the operation of the spreader tip of the surgical mesh applicator of Figure 3;

Figure 27 is a distal end view of the expanded spreader tip; and

Figure 28 is a proximal end view of a finger grip on the surgical mesh applicator of Figure 3.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0022] Referring to Figure 1, the present invention is embodied in an applicator or delivery device, generally 50, including an expandable spreader tip 60 which is insertable through an incision or a natural body orifice to enable a surgeon to apply a sheet 65 (Figure 6) of surgical material, such as a surgical mesh or an adhesion barrier, to tissue inside the body. The applicator 50 is particularly suitable for use by a surgeon to apply the surgical mesh 65 to internal body tissue at a site where a surgical repair, e.g., a hernia operation, is to be performed. The surgical mesh 65 can be made of a material such as rayon which has a tendency to stick to the internal body tissue or a non-wetting material such as polypropylene.

[0023] As shown in Figure 1, the surgical mesh applicator 50 includes a pair of elongated tubes 100 and 102 which are telescoped together for longitudinal movement relative to each other. Preferably, the outer tube 100 consists of clear plastic material and, if desired, the

tube 102 is made of the same material. The outer tube 100 is secured at its proximal end to a finger grip 104. The outer tube 100 constitutes a delivery tube through which the spreader tip 60 and the surgical mesh 65 is inserted into the body. The inner tube 102 is slidably received by the outer delivery tube 100 and is freely rotatable about the longitudinal axis of the delivery tube 100. The inner tube 102 serves as a deployment tube for actuating the spreader tip 60 and applying the surgical mesh 65 to internal body tissue.

[0024] Inside the deployment tube 102 is an elongated shaft or push rod 106 (Figure 5) which projects beyond the distal end of the deployment tube 102 and supports the expandable spreader tip 60. The deployment tube 102 is slidable longitudinally relative to the push rod 106 to expand the spreader tip 60 to spread the surgical mesh 65 over the internal body tissue. Preferably, the push rod 106 is a hollow shaft and serves as an irrigation tube for supplying fluid to the surgical mesh 65. For example, the push rod 106 is made of metal, such as stainless steel.

[0025] A fluid coupling member 105 for connection to a source of fluid (not shown) is attached to the proximal end of the hollow push rod 106. For example, the fluid coupling member 105 consists of a hollow cylindrical element made of plastic and known as a "Luer Lok" which is adapted to receive a syringe or a compressible bulb for supplying fluid via the hollow push rod 106 to the spreader tip 60.

The deployment tube 102 has a longitudinal slot 108 (Figure 4) extending distally for a predetermined length from the proximal end of the tube 102. The longitudinal slot 108 terminates at a distal edge 110 (Figure 5). A latch ring 112 is slidably mounted on the deployment tube 102 and is slidably received in the longitudinal slot 108 for movement therealong relative to the deployment tube 102. As shown in Figure 8, the latch ring 112 comprises a hollow cylindrical wall 114 including a longitudinal notch 115. A depending flange 116 is secured in the notch 115 and is slidably received in the longitudinal slot 108 of the deployment tube 102. The depending flange 116 supports an inner cylindrical member 118 which is slidably received inside the deployment tube 102. The cylindrical member 118 has an axial bore 120 (Figure 5) in which the push rod 106 is secured.

[0027] A first actuator member comprising an annular delivery flange 122 is slidably mounted on the deployment tube 102. The annular delivery flange 122 is slidably received in the longitudinal slot 108 for movement therealong relative to the deployment tube 102. As shown in Figure 9, the delivery flange 122 includes a longitudinal notch 123 in which a depending flange 124 is secured. The depending flange 124 is slidably received in the longitudinal slot 108 of the deployment tube 102. The depending arm 124 supports an inner cylindrical member 126 which is slidably received inside the deployment tube 102. The cylindrical member 126

has an axial bore 128 (Figure 5) for slidably receiving the push rod 106.

A second actuator member comprising an [0028] annular deployment flange 130 is secured to the proximal end of the deployment tube 102. An elongated compression coil spring 132 is mounted on the push rod 106 and interposed between the delivery flange 122 and the deployment flange 130. The proximal end of the compression spring 132 is received in an axial counterbore 134 formed in the deployment flange 130. The distal end of the compression spring 132 is engaged with a flat rear surface 136 on the inner cylindrical member 126 of the delivery flange 122. The delivery flange 122 has a flat front surface 138 which is urged by the compression spring 132 into contact with the rear cylindrical wall 114 of the latch ring 112. The latch ring 112 and the delivery flange 122 are normally biased toward the distal end 110 of the longitudinal slot 108 by the compression coil spring 132. An outwardly tapered collar 140 at the front of the latch ring 112 defines an annular lip 142 for securing the latch ring 112 to the finger grip 104 when the deployment tube 102 is advanced.

[0029] As shown in Figure 3, the finger grip 104 includes a hollow cylindrical body 150 connected to a rear funnel-shaped flange 152 which facilitates the insertion of the spreader tip 60 and the deployment tube 102 into the delivery tube 100. The cylindrical body 150 has a counterbore 154 in which the proximal end of the delivery tube 100 is secured. A latch arm 156 is mounted on a pivot pin 158 which extends transversely between a pair of upstanding longitudinal flanges 160 (Figure 4) extending along opposite sides at the top of the cylindrical body 150 of the finger grip 104. The latch arm 156 is located in a longitudinal slot 162 (Figure 5) which extends between the flanges 160 into the funnel-shaped flange 152 and allows the latch arm 156 to engage thè deployment tube 102.

[0030] As shown in Figure 5, the latch arm 156 projects upwardly from the finger grip 104 to provide a finger rest for engagement by the index finger of the surgeon. A depending latch finger 164 is provided at the rear of the latch arm 156 for latching the annular lip 142 when the latch ring 112 is advanced into the funnelshaped flange 152 (Figure 6) of the finger grip 104. The latch finger 164 has a beveled edge 166 (Figure 5) which rides along the tapered collar 140 of the latch ring 112 to pivot the latch arm 156 and allow the latch finger 164 to move over and engage the annular lip 142 when the delivery tube 100 is retracted to expose the spreader tip 60 at the distal end of the delivery tube 100. The latch arm 156 has a release lever 168 at its distal end which is biased upwardly from the cylindrical body 150 by a coil spring 170. The annular lip 142 is movable into engagement with the latch finger 164 in any rotational orientation of the deployment 102 relative to the delivery tube 100 to retain the delivery tube 100 in the retracted position. The annular lip 142 permits the deployment tube 102 and the push rod 106 to be rotated

relative to the delivery tube 100 with the delivery tube 100 latched in the retracted position to adjust the angular orientation of the spreader tip 60.

[0031] A detent 172 is provided on the latch arm 156 for engagement with an annular groove 174 formed in the deployment tube 102 to hold the spreader tip 60 in a retracted position inside the distal end of the delivery tube 100. The annular groove 174 is engageable by the detent 172 in any rotational orientation of the deployment tube 102 relative to the delivery tube 100 to retain the spreader tip 60 inside the delivery tube 100. Also, the annular groove 174 permits the deployment tube 102 and the push rod 106 to be rotated relative to the delivery tube 100 with the delivery tube 100 latched in the retracted position to adjust the rotational or angular orientation of the spreader tip 60. On one side of the latch arm 156 is a stop 176 (Figure 28) which is biased into engagement with the funnel-shaped flange 152 when the deployment tube 102 is removed from the delivery tube 100 to limit the pivotal movement of the latch arm 156 by the coil spring 170.

[0032] Referring to Figure 3, the spreader tip 60 comprises an expandable basket-like frame made of flexible material, e.g., thin strips of stainless steel. The spreader tip 60 has a plurality of flexible frame members or strips 62 of stainless steel extending longitudinally between a first retainer 64 secured to the distal end of the deployment tube 102 and a second retainer 66 secured to the distal end of the shaft or push rod 106. Preferably, each of the flexible strips 62 is pivotally connected at its opposite ends to the retainers 64 and 66. Each end of the flexible stainless steel strips 62 is folded over itself to provide a flap 68 (Figure 10) which is attached, e.g., by spot welding, to the strip 62. Each flap 68 provides a hinge-like connection for pivotally attaching the opposite ends of the strip 62 to the retainers 64 and 66 at the distal ends of the push rod 106 and the deployment tube 102, respectively.

[0033] As shown in Figure 6, the spreader tip 60 is collapsed with the flexible strips 62 extending generally parallel to the push rod 106 when the proximal retainer 64 is displaced in the proximal direction away from the distal retainer 66. The spreader tip 60 is expanded (Figure 7) with the flexible strips 62 bulging radially outward when the proximal retainer 64 is displaced in the distal direction toward the distal retainer 66. In the relaxed or collapsed configuration of the spreader tip 60 (Figure 6), each strip 62 is slightly bent and extends radially outward at its midpoint 69 away from the push rod 106. When the spreader tip 60 is actuated (Figure 7), the strips 62 are flexed laterally outward into a convex shape to spread the surgical material over the tissue. Preferably, the longitudinal strips 62 are spaced circumferentially about the spreader tip 60 at equal intervals. For example, as shown in Figure 27, the four strips 62 are spaced apart at intervals of 90 degrees.

[0034] As shown in Figure 10, the proximal retainer 64 has an elongated, hollow body 70 of generally cylindri-

cal shape having an axial bore 71 extending therethrough in which the push rod 106 is slidably received. As shown in Figures 14 and 15, the sides of the retainer body 70 are cut away to form four longitudinal channels 72 spaced circumferentially apart by 90 degrees. Also, four radially extending flanges 73 are formed on the retainer body 70 and disposed between the longitudinal channels 72. The flanges 73 engage the distal end of the deployment tube 102 with the retainer 64 inserted therein. The retainer body 70 includes a conically tapered distal end portion 74. Adjacent to the distal side of the flanges 73 is a circumferential groove 75 for receiving a retainer ring 76 to which the proximal ends of the strips 62 are pivotally connected. As shown in Figure 16, the ring 76 has four rounded corners 77 located in the portions of the groove 75 adjacent to the flanges 73 and four straight portions 78 to which the hinge-like flaps 68 of the strip 62 are pivotally attached. [0035] Referring to Figure 10, the distal retainer 66 comprises an elongated, hollow body 80 of generally cylindrical shape having an axial bore 81 extending therethrough in which the distal end of the push rod 106 is secured. As shown in Figures 11 and 12, the sides of the retainer body 80 are cut away to form four longitudinal channels 82 spaced circumferentially apart by 90 degrees. Also, four radially extending flanges 83 are formed on the retainer body 80 and disposed between the longitudinal channels 82. The retainer body 80 includes a conically tapered distal end portion 84. Adjacent to the proximal side of the flanges 83 is a circumferential groove 85 for receiving a retainer ring 86 to which the distal ends of the strips 62 are pivotally connected. As shown in Figure 13, the ring 86 has four rounded corners 87 located in the portions of the groove 85 adjacent to the flanges 83 and four straight portions 88 to which the hinge-like flaps 68 of the strip 62 are pivotally attached.

[0036] As shown in Figure 10, a tissue manipulating nozzle or pad 90 is provided at the distal end of the spreader tip 60. Preferably, the pad 90 is generally cylindrical in shape and constructed from a soft pliable material, e.g., a polymeric material such as silicon, urethane or a latex, or a rubber material. The cylindrical pad 90 is adhered to the front face of the distal retainer 66 and provided with a central opening or port 91 through which a saline solution can be applied to the sheet of surgical material 65.

[0037] The cylindrical pad 90 includes a series of circumferentially spaced, distally projecting protuberances or prongs 92 formed on its front face. Preferably, the prongs 92 are cylindrical in shape and provided with rounded or pointed tips for engaging the surgical material. The prongs 92 serve as fabric engaging fingers which allow the sheet of surgical material 65 to be displaced and rotated by manipulation of the spreader tip 60. Because of the soft pliable material of the pad 90, the prongs 92 grasp the surgical mesh or other material with sufficient friction to enable the surgical mesh to be

moved over the internal body tissue by manipulation of the instrument 50. Also, in the case of a surgical mesh 65 with large size openings or holes (Figure 18), the prongs 92 fit inside the holes of the mesh 65 to enhance the fabric grasping action of the prongs 92. By appropriate manipulation of the instrument 50, the surgical mesh 65 can be rotated or slid across the internal body tissue to adjust the desired position of the mesh 65 on the tissue.

[0038] In the preferred embodiment of the surgical mesh applicator 50, the delivery tube 100 and the deployment tube 102 consist of plastic material and the shaft or push rod 106 is made of stainless steel. The flexible strips 62, the retainers 64 and 66, and the retainer rings 76 and 86 of the spreader tip 60 are also made of stainless steel. The finger grip 104 and the latch arm 156 are made of plastic material. Also, the latch ring 112, the delivery flange 122 and the deployment flange 130 are made of plastic material.

In the operation of the surgical applicator 50. the deployment tube 102 is removed from the delivery tube 100 and a sheet of surgical mesh 65 is centered over the mouth of the funnel-shaped flange 152 (Figure 23). The deployment tube 102 is aligned longitudinally with the delivery tube 100 and the collapsed spreader tip 60 is positioned adjacent to the surgical mesh 65 and pointed toward the funnel-shaped flange 152. The fluid coupling member 105 (or delivery button) and the deployment flange 130 are held together by the thumb and two fingers, respectively, so that the flexible strips 62 of the spreader tip 60 remain in the collapsed condition. The push rod 106 and the deployment tube 102 are advanced distally through the funnel-shaped flange 152 into the delivery tube 100. The surgical mesh 65 is pushed into the delivery tube 100 and folded over the spreader tip 60 by the funnel-shaped flange 152. The spreader tip 60 and surgical mesh 65 are advanced distally by sliding the deployment tube 102 and the push rod 106 along the delivery tube 100 until the spreader tip 60 is stopped in a retracted position (Figure 5) inside the distal end of the delivery tube 100 by the engagement of the detent 172 on the latch arm 156 with the annular groove 174 in the deployment tube 102.

[0040] Next, the surgical instrument 50 is introduced into a body cavity by inserting the delivery tube 100 into a trocar tube (not shown) which extends through an incision in the body wall. The distal end of the delivery tube 100 is positioned against the tissue T (Figure 24) at the site where the surgical mesh 65 is to be applied. Then, by placing one finger through the finger grip 104 and a thumb on the proximal side of the delivery flange 122, the delivery tube 100 is retracted by pulling on the finger grip 104 while counter pressure is applied to the delivery flange 122 to maintain the distal end of the spreader tip 60 at the surgical site. The delivery flange 122 is pressed against the latch ring 112 to urge the deployment tube 102 and the push rod 106 distally as the delivery tube 100 is retracted. When the delivery tube

100 is completely retracted, the latch finger 164 on the latch arm 156 engages the annular lip 142 on the latch ring 112 to latch the delivery tube 100 in its retracted position (Figure 6) with the spreader tip 60 and the surgical mesh 65 exposed at the distal end of the delivery tube 100. The surgical mesh 65 is held against the tissue T (Figure 25) by the pressure exerted on the spreader tip 60.

[0041] Next, the deployment tube 102 is advanced distally relative to the delivery tube 100 and to the push rod 106 by pushing the deployment flange 130 in the distal direction. The deployment tube 102 is advanced distally until the spreader tip 60 is fully expanded, i.e., with the proximal retainer 64 engaged with the distal retainer 66 and the flexible strips 62 flexed outwardly into the fully expanded configuration (Figure 7). The outwardly flexed strips 62 of the spreader tip 60 spread the surgical mesh 65 over the tissue T (Figure 26) at the surgical site. The latch ring 112 and the delivery flange 122 constitute a split actuator which prevents the push rod 106 from being pulled in the proximal direction as the spreader tip 60 is expanded. If any pulling force is applied to the delivery flange 122 when the latch ring 112 is latched by the latch arm 156, the delivery flange 122 merely slides proximally along the slot 108 away from the latch ring 112 without pulling on the push rod 106. Then, while holding the surgical mesh 65 against the tissue T with the expanded spreader tip 60, the surgical mesh 65 is fastened to the tissue T, e.g., by sutures or staples. A saline solution can be applied via the irrigation tube 106 and the nozzle 90 to maintain the surgical mesh 65 in place on the surgical site. Also, the surgical mesh 65 can be repositioned on the tissue T by placement of the nozzle 90 with its prongs 92 engaging the surgical mesh 65 and by sliding or rotating the nozzle 90 on the tissue T.

[0042] After the surgical mesh 65 is attached to the tissue T, the deployment flange 130 is released and allowed to return to its proximal position by the coil spring 132. The flexible strips 62 of the spreader tip 60 are collapsed to facilitate the extraction of the surgical instrument 50 from the trocar tube. The surgical instrument 50 is removed by pulling on the finger grip 104 and latch arm 156 to slide the entire instrument 50 out of the trocar tube at one time.

[0043] The surgical mesh applicator 50 is adapted for use with a relatively large and thick sheet 65 of surgical mesh. The spreader tip 60 can be used to apply a sheet 65 of surgical material which is rectangular in shape and up to twice as long as the flexible arms 62. When the sheet 65 of surgical material is folded over the spreader tip 60 and inserted into the delivery tube 100, the folded surgical material does not extend beyond the proximal end of the spreader tip 60 so that the possibility of binding of the surgical material between the delivery tube 100 and the deployment tube 102 is avoided. Also, the spreader tip 60 can be used to apply a sheet 65 of surgical material which is circular in shape with a

diameter up to twice the length of the flexible arms 62.

[0044] The shaft or push rod 106 has a small diameter in comparision with the deployment tube 102 and the delivery tube 100 and the thin flexible strips 62 of stainless steel provide sufficient space inside the delivery tube 100 to permit a relatively large and thick surgical mesh 65 to be folded over the spreader tip 60 and inserted into the tube 100. For example, each of the flexible strips 62 consists of stainless steel shim stock which is approximately 0.005 inch thick and 0.100 inch wide. Each flexible strip 62 has a finished length of approximately 2.750 inches between the hinge-like connections at its opposite ends.

[0045] Referring to Figure 19, a modified embodiment of the surgical mesh applicator 50 is provided with a pick-up mechanism comprising a wire 200 slidably received inside the hollow push rod 106. The wire 200 extends through the central opening 91 in the tissue manipulating pad 90 and includes a hook 202 at its distal end for engaging the surgical mesh 65. The hook 202 is adapted to snare the surgical mesh 65 against the pad 90 to allow the mesh 65 to be picked up from the abdominal wall and maneuvered into a desired position. For example, the wire 200 comprises a thin hair-like wire spring steel having a curved distal end to provide the hook 202 for engaging the surgical mesh 65. Alternatively, the wire 200 consists of a polymer material which is thermally set or molded to form the hook 202 at its distal end. The wire 200 extends longitudinally along the inside of the push rod 106 and emerges from the proximal end of the push rod 106. An actuator in the form of a push-pull mechanism (not shown) is provided at the proximal end of the surgical mesh applicator 50 to actuate the pick-up wire 200.

[0046] In the operation of the embodiment of Figure 18, the surgical mesh 65 is spread over the opening in the funnel-shaped flange 152 at the proximal end of the delivery tube 100. The spreader tip 60 is placed against the surgical mesh 65 and aligned with the opening in the funnel-shaped flange 152. As shown in Figure 20, the pick- up wire 200 is initially retracted inside the push rod 106. Then, the pickup wire 200 is advanced distally to advance the hook 202 through the central opening 91 in the tissue manipulating pad 90. As the wire 200 is advanced, the distal end of the wire 200 curves into an arc of predetermined radius to form the hook 202 (Figure 21). With the tissue manipulating pad 90 flush against the surgical mesh 65, the distal end of the wire 200 passes through the surgical mesh 65 and curves to form the hook 202 which snares the surgical mesh 65. Then, the spreader tip 60 and the push rod 106 are advanced distally into the delivery tube 100 to push the surgical mesh 65 into the delivery tube 100. The applicator 50 is inserted into a trocar or endoscopic tube and aligned with the desired placement site. The surgical mesh 65 is deployed by actuating the delivery flange 122 to expose the spreader tip 60 at the distal end of the delivery tube 102 and by acutating the deloyment flange

130 to expand the spreader tip 60 to spread the mesh 65 over the tissue. Because the surgical mesh 65 is snared by the hook 202, the mesh 65 can be lifted from the tissue by manipulating the applicator 50 and placed in a desired position on the tissue without disengagement from the spreader tip 60. After the surgical mesh 65 is placed in the desired position, the hook 202 can be withdrawn from the surgical mesh 65 by retracting the wire 200 into the hollow push rod 106.

[0047] Referring to Figure 22, in another embodiment of the surgical mesh applicator 50, a solid shaft or push rod 206 is used in place of the hollow push rod or irrigation tube 106 previously described. A delivery button 205 is secured to the proximal end of the shaft 206 in place of the fluid coupling member 105 previously described. Otherwise, the surgical mesh applicator 50 of Figure 22 includes substantially the same components described above which are identified by the same reference numerals previously used. The embodiment of Figure 22 is used to apply a non-wetting surgical mesh, e.g., a polypropylene mesh, to internal body tissue.

[0048] The invention in its broader aspects is not limited to the specific details of the preferred embodiments shown and described, and those skilled in the art will recognize that the invention can be practiced with modification within the scope of the appended claims.

Claims

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 An applicator (50) for applying a spreadable sheet 65 of surgical material to internal body tissue, comprising:

a delivery tube (100);

a deployment tube (102) slidably received within said delivery tube (100);

a shaft (106) slidably received within said deployment tube (102), said shaft (106) having a distal end projecting from the distal end of said deployment tube (102);

an expandable spread tip (60) mounted at the distal end of said shaft (106) and connected to the distal end of said deployment tube (102) for spreading the sheet 65 of surgical material over the tissue, said spreader tip (60) being collapsed when inserted in said delivery tube (100) with said surgical material;

means for retracting said delivery tube (100) relative to said deployment tube (102) and said shaft (106) to expose said spreader tip (60) and said surgical material at said distal end of said delivery tube (100);

characterised in that said applicator also comprises

first actuator means (122) for urging said spreader tip (60) and surgical material into engagement with the tissue as said deploy-

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ment tube (102) is retracted; and second actuator means (130) for advancing said deployment tube (102) relative to said shaft (106) to expand said spreader tips (60) to apply the surgical material to the tissue.

2. The applicator (50) of Claim 1, which includes:

a return spring for biasing said deployment tube (102) in the proximal direction relative to said shaft (106) to normally maintain said spreader tip (60) collapsed.

The applicator (50) of Claim 1, wherein said spreader tip (60) comprises:

a plurality of flexible strips (62) each being pivotally connected at its opposite ends to said distal end of said shaft (106) and to said distal end of said deployment tube (102), said strips (62) being flexed outwardly when said deployment tube (102) is advanced relative to said shaft (106) to spread the surgical material over the tissue.

4. The applicator (50) of Claim 1, wherein:

said spreader tip (60) includes a plurality of distally extending prongs (92) for engaging the sheet (65) of surgical material to adjust the placement of the surgical material on the tissue.

5. The applicator (50) of claim 1, wherein:

said deployment tube (102) and said shaft (106) are rotatable together relative to said delivery tube (100) to adjust the angular orientation of said spreader tip (60) and the surgical material.

6. The applicator (50) of Claim 5, wherein:

said deployment tube (102) and said shaft (106) are rotatable together when said spreader tip (60) is collapsed inside said delivery tube (100) and when said spreader tip (60) is expanded outside said delivery tube (100).

7. The applicator (50) of Claim 1, which includes:

latch means for latching said delivery tube (100) in a retracted position with said spread (60) and said surgical material exposed at said distal end of said delivery tube (100).

8. The applicator (50) of Claim 7, wherein:

said latch means is operable in any rotational orientation of said deployment tube (102) relative to said delivery tube (100) to latch said delivery tube (100) in the retracted position.

9. The applicator (50) of Claim 7, wherein:

said latch means is adapted to permit rotation of said deployment tube (102) and said shaft (106) relative to said delivery tube (100) with said delivery tube (100) latched in the retracted position.

10. The applicator (50) of Claim 9, wherein said latch means comprises:

a latching member (156) on said delivery tube (100) and

a latch ring (112) on said deployment tube (102) adapted to engage said latching member (164) in any rotational orientation of said deployment tube (102) relative to said delivery tube (100) when said delivery tube (100) is moved to the retracted position.

11. The applicator (50) of Claim 1, which includes:

detent means for releaseably engaging said deployment tube (102) to retain said spreader tip (60) inside said delivery tube (100) prior to the exposure of said spreader tip (60) therefrom.

12. The applicator (50)of Claim 11, wherein:

said detent means is operable in any rotational orientation of said deployment tube (102) relative to said delivery tube (100) to retain said spreader tip (60) inside said delivery tube (100).

13. The applicator (50) of Claim 11, wherein:

said detent means is adapted to permit rotation of said deployment tube (102) and shaft (106) relative to said delivery tube (100) with said spreader tip (60) retained inside said delivery tube (100).

14. The applicator (50) of Claim 13, wherein said detent means comprises:

a latching member (156) on said delivery tube (100) and

an annular groove (174) on said deployment tube (102) adapted to engage said latching member (156) in any rotational orientation of said deployment tube (102) relative to said said

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delivery tube (100) when said spreader tip (60) is retracted.

15. The applicator (50) of Claim 1, which includes:

a hollow funnel-shaped flange (152) at the proximal end of said delivery tube (100) for guiding said spreader tip (60) and the surgical material into said delivery tube (100).

16. The applicator (50) of Claim 1, wherein:

said shaft (106) comprises an irrigation tube for supplying fluid to the sheet (65) of surgical material.

17. The applicator (50) of Claim 16, which includes:

a nozzle (90) at the distal end of said irrigation tube for discharging the fluid therefrom.

18. The applicator (50) of Claim 17, wherein:

said nozzle (90) includes a plurality of distally extending prongs (92) for engaging the sheet (65) of surgical material to adjust the placement of the surgical material on the tissue.

19. The applicator (50) of Claim 1, which includes:

a pick-up mechanism for securing the sheet (65) of surgical material to said spreader tip (60).

20. The applicator (50) of Claim 19, wherein:

said pickup mechanism comprises a wire (200) slidably mounted on said spreader tip (60) and provided with a hook (202) for engaging the surgical material to snare the surgical material on said spreader tip (60).

Patentansprüche

 Applikator zum Anbringen einer ausbreitbaren Lage (65) aus chirurgischem Material auf innerem K\u00f6rpergewebe umfassend:

ein Zufuhrrohr (100);

ein Entfaltungsrohr (102), welches gleitend in dem Zufuhrrohr (100) untergebracht ist;

einen gleitend in dem Entfaltungsrohr (102) untergebrachten Stab (106), wobei ein distales Ende des Stabes (106) aus dem distalen Ende des Entfaltungsrohres (102) herausragt; einen aufklappbaren Ausbreitungskopf (60), der am distalen Ende des Stabes (106) angebracht und mit dem distalen Ende des Entfaltungsrohres (102) verbunden ist, um die Lage (65) des chirurgischen Materials über dem Gewebe auszubreiten, wobei der Ausbreitungskopf (60) zusammengeklappt ist, wenn er mit dem chirurgischen Material im Zufuhrrohr (100) untergebracht ist;

eine Einrichtung zum Zurückziehen des Zufuhrrohres (100) relativ zum Entfaltungsrohr (102) und zum Stab (106), um den Ausbreitungskopf (60) sowie das chirurgische Material am distalen Ende des Zufuhrrohres (100) freizulegen;

dadurch gekennzeichnet, daß der Applikator weiterhin umfaßt:

eine erste Betätigungseinrichtung (122), um den Ausbreitungskopf (60) und das chirurgische Material am Gewebe zur Anlage zu bringen, wenn das Entfaltungsrohr (102) zurückgezogen wird und

eine zweite Betätigungseinrichtung (130), um das Entfaltungsrohr (102) relativ zu dem Stab (106) vorzuschieben und dadurch den Ausbreitungskopf (60) aufzuklappen und das chirurgische Material auf dem Gewebe anzubringen.

- Applikator (50) nach Anspruch 1, welcher eine Rückholfeder zum Vorspannen des Entfaltungsrohres (102) in proximaler Richtung relativ zum Stab (106) aufweist, um den Ausbreitungskopf (60) normalerweise zusammengeklappt zu halten.
- Applikator (50) nach Anspruch 1, bei welchem der Ausbreitungskopf (60) umfaßt:

eine Vielzahl flexibler Streifen (62), deren jeder mit seinen beiden entgegengesetzten Ende schwenkbar am distalen Ende des Stabes (106) und am distalen Ende des Entfaltungsrohres (102) angebracht ist, wobei diese Streifen (62) nach außen gebogen werden, wenn das Entfaltungsrohr (102) relativ zu dem Stab (106) vorgeschoben wird, um das chirurgische Material auf dem Gewebe auszubreiten.

4. Applikator (50) nach Anspruch 1, bei welchem:

der Ausbreitungskopf (60) eine Vielzahl sich in distaler Richtung erstreckender Zacken (92) zur Anlage an der Lage (65) aus chirurgischem Material aufweist, um die Plazierung des chirurgischen Materials auf dem Gewebe auszurichten.

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5. Applikator (50) nach Anspruch 1, bei welchem:

. das Entfaltungsrohr (102) und der Stab (106) zusammen relativ zum Zufuhrrohr (100) drehbar sind, um die Winkelorientierung des Ausbreitungskopfes (60) und des chirurgischen Materials einzustellen.

6. Applikator (50) nach Anspruch 5, bei welchem:

das Entfaltungsrohr (102) und der Stab (106) zusammen drehbar sind, wenn sich der Ausbreitungskopf (60) zusammengeklappt im Inneren des Zufuhrrohres (100) befindet und wenn der Ausbreitungskopf (60) außerhalb des Zufuhrrohres(100) aufgeklappt ist.

7. Applikator (50) nach Anspruch 1, welcher aufweist:

eine Rasteinrichtung zum Einrasten des Zufuhrrohres (100) in einer zurückgezogenen Stellung, wobei der Ausbreitungskopf (60) und das chirurgische Material am distalen Ende des Zufuhrrohres (100) freiliegen.

8. Applikator (50) nach Anspruch 7, bei welchem:

die Rasteinrichtung in jeder Drehstellung des Entfaltungsrohres (102) relativ zum Zufuhrrohr (100) betätigbar ist, um das Zufuhrrohr (100) in der zurückgezogenen Stellung einzurasten.

9. Applikator (50) nach Anspruch 7, bei welchem:

die Rasteinrichtung derart aufgebaut ist, daß sie die Drehung des Entfaltungsrohres (102) und des Stabes (106) relativ zum Zufuhrrohr (100) ermöglicht, wobei das Zufuhrrohr (100) in der zurückgezogenen Stellung eingerastet ist.

 Applikator (50) nach Anspruch 9, bei welchem die Rasteinrichtung umfaßt:

ein Rastelement (156) auf dem Zufuhrrohr (100) und

einen Rastring (112) auf dem Entfaltungsrohr (102), welcher derart aufgebaut ist, daß er in jeder Drehstellung des Entfaltungsrohres (102) relativ zum Zufuhrrohr (100) in das Rastelement (164) eingreift, wenn das Zufuhrrohr (100) in die zurückgezogene Stellung bewegt wird.

11. Applikator (50) nach Anspruch 1, welcher aufweist:

eine Arretierungseinrichtung zum lösbaren Eingriff in das Entfaltungsrohr (102), um den Ausbreitungskopf (60) im Inneren des Zufuhrrohres (100) vor der Freilegung des Ausbreitungskopfes (60) zu halten.

12. Applikator (50) nach Anspruch 11, bei welchem:

die Arretierungseinrichtung in jeder Drehstellung des Entfaltungsrohres (102) relativ zum Zufuhrrohr (100) betätigbar ist, um den Ausbreitungskopf (60) im Inneren des Zufuhrrohres (100) zu halten.

13. Applikator (50) nach Anspruch 11, bei welchem:

die Arretierungseinrichtung derart aufgebaut ist, daß die Drehung des Entfaltungsrohres (102) und des Stabes (106) relativ zum Zufuhrrohr (100) möglich ist, wobei der Ausbreitungskopf (60) im Inneren des Zufuhrrohres (100) gehalten wird.

14. Applikator nach Anspruch 13, bei welchem die Arretierungseinrichtung umfaßt:

ein Rastelement (156) auf dem Zufuhrrohr (100) und

eine umlaufende Rille (174) auf dem Entfaltungsrohr (102), welche für den Eingriff des Rastelementes (156) in jeder Drehorientierung des Entfaltungsrohres (102) relativ zum Zufuhrrohr (100) eingerichtet ist, wenn der Ausbreitungskopf (60) zurückgezogen wird.

15. Applikator (50) nach Anspruch 1, welcher aufweist:

einen hohlen trichterförmigen Flansch (152) am proximalen Ende des Zufuhrrohres (100), um den Ausbreitungskopf (60) und das chirurgische Material in das Zufuhrrohr (100) einzuführen.

16. Applikator (50) nach Anspruch 1, bei welchem:

der Stab (106) ein Befeuchtungsrohr zur Zufuhr von Flüssigkeit zur Lage (65) des chirurgischen Materials umfaßt.

 Applikator (50) nach Anspruch 16, welcher aufweist:

eine Düse (90) am distalen Ende des Befeuchtungsrohres, um von dort die Flüssigkeit freizusetzen.

18. Applikator (50) nach Anspruch 17, bei welchem:

die Düse (90) eine Vielzahl sich in distaler

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Richtung erstreckender Zacken (92) zur Anlage an der Lage (65) aus chirurgischem Material aufweist, um die Plazierung des chirurgischen Materials auf dem Gewebe auszurichten.

19. Applikator (50) nach Anspruch 1, welcher aufweist:

einen Aufnehmermechanismus zum Sichern der Lage (65) des chirurgischen Materials auf dem Ausbreitungskopf (60).

20. Applikator (50) nach Anspruch 19, bei welchem:

der Aufnehmermechanismus einen Draht (200) umfaßt, der gleitend in dem Ausbreitungskopf (60) untergebracht und mit einem Haken (202) versehen ist, um sich an das chirurgische Material anzulegen und dasselbe um den Ausbreitungskopf (60) zu legen.

Revendications

 Applicateur (50) pour appliquer une feuille pouvant être étendue (65), constituée d'un matériau chirurgical, sur un tissu corporel interne, comportant :

un tube d'alimentation (100),

un tube de déploiement (102) reçu de manière coulissante dans ledit tube d'alimentation (100).

un arbre (106) reçu de manière coulissante dans ledit tube de déploiement (102), ledit arbre (106) ayant une extrémité distale faisant saillie à partir de l'extrémité distale dudit tube de déploiement (102),

un bout expansible (60) de dispositif d'étalement monté au niveau de l'extremité distale dudit arbre (106) et relié à l'extremité distale dudit tube de déploiement (102) pour étaler la feuille (65) de matérieau chirurgical sur le tissu, ledit bout (60) de dispositif d'étalement étant en position repliée lorsqu'il est inséré dans ledit tube d'alimentation (100) avec ledit matériau chirurgical.

des moyens pour rétracter ledit tube d'alimentation (100) par rapport audit tube de déploiment (102) et audit arbre (106) pour exposer ledit bout (60) de dispositif d'étalement et ledit matériau chirurgical au niveau de ladite extrémité distale dudit tube d'alimentation (100),

caractérisé en ce que ledit applicateur comporte aussi :

des premiers moyens d'actionnement (122) destinés à repousser ledit bout (60) de dispositif d'étalement et le matériau chirurgical en contact avec le tissu lorsque ledit tube de déploiement (102) est rétracté, et des seconds moyens d'actionnement (130) pour faire avancer ledit tube de déploiement (102) bar rapport audit arbre (106) pour expanser ledit bout (60) de dispositif d'étalement pour appliquer le matériau chirurgical sur le tissu.

Applicateur (50) selon la revendication 1, qui comporte :

> un ressort de rappel pour rappeler ledit tube de déploiement (102) dans la direction proximale par rapport audit arbre (106) pour maintenir normalement en position repliée ledit bout (60) de dispositif d'étalement.

 Applicateur (50) selon la revendication 1, dans lequel ledit bout (60) de dispositif d, étalement comporte :

plusieurs bandes souples (162), chacune étant reliée de manière pivotante à ses extrémités opposées à ladite extrémité distale dudit arbre (106) et à ladite extrémité distale dudit tube de déploiement (102), lesdites bandes (62) étant incurvées vers l'extérieur lorsque ledit tube de déploiement (102) est avancé par rapport audit arbre (110) pour étaler le matériau chirurgical sur le tissu.

 Applicateur (50) selon la revendication 1, dans lequel:

> ledit bout (60) de dispositif d'étalement comporte plusieurs dents (92) s'étendant distalement destinées à venir en contact avec la feuille (65) de matériau chirurgical pour ajuster le positionnement du matériau chirurgical sur le tissu.

Applicateur (50) selon la revendication 1, dans lequel:

ledit tube de déploiement (102) et ledit arbre (106) peuvent tourner ensemble par rapport audit tube d'alimentation (100) pour ajuster l'orientation angulaire dudit bout (60) de dispositif d'étalement et du matériau chirurgical.

50 6. Applicateur (50) selon la revendication 5, dans lequel:

ledit tube de déploiement (102) et ledit arbre (106) peuvent tourner ensemble lorsque ledit bout (60) de dispositif d'étalement est en position repliée à l'intérieur dudit tube d'alimentation (100) et lorsque ledit bout (60) de dispositif d'étalement est expansé à l'extérieur dudit tube

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d'alimentation (100).

Applicateur (50) selon la revendication 1, qui comporte :

des moyens de verrouillage pour verrouiller ledit tube d'alimentation (100) dans une position rétractée, ledit bout (60) de dispositif d'étalement et ledit matériau chirurgical étant exposés au niveau de ladite extrémité distale dudit tube d'alimentation (100).

8. Applicateur (50) selon la revendication 7, dans lequel:

lesdits moyens de verrouillage peuvent être actionnés dans toute orientation en rotation dudit tube de déploiement (102) par rapport audit tue d'alimentation (100) pour verrouiller ledit tube d'alimentation (100) dans la position rétractée.

Applicateur (50) selon la revendication 7, dans lequel:

lesdits moyens de verrouillage sont adaptés pour permettre une rotation dudit tube de déploiement (102) et dudit arbre (106) par rapport audit tube d'alimentation (100), ledit tube d'alimentation (100) étant verrouillé dans la position rétractée.

10. Applicateur (50) selon la revendication 9, dans lequel lesdits moyens de verrouillage comportent:

un élément de verrouillage (152) situé sur le-dit tube d'alimentation (100) et un anneau de verrouillage (112) situé sur ledit tube de déploiement (102) adapté pour venir en prise avec ledit élément de verrouillage (152) dans toute orientation en rotation dudit tube de déploiement (102) par rapport audit tube d'alimentation (100) lorsque ledit tube d'alimentation (100) est déplacé vers la position rétractée.

 Applicateur (50) selon la revendication 1, qui comporte :

des moyens d'arrêt pour venir en prise de manière libérable avec ledit tube de déploiement (102) pour retenir ledit embout (60) de dispositif d'étalement à l'intérieur dudit tube d'alimentation (100) avant d'exposer ledit embout (60) de dispositif d'étalement à partir de celui-ci.

Applicateur (50) selon la revendication 11, dans lequel:

lesdits moyens d'arrêt peuvent être actionnés dans toute orientation en rotation dudit tube de déploiement (102) par rapport audit tube d'alimentation (100) pour retenir ledit embout (60) de dispositif d'étalement à l'intérieur dudit tube d'alimentation (100).

Applicateur (50) selon la revendication 11, dans lequel:

lesdits moyens d'arrêt Sont adaptés pour permettre la mise en rotation dudit tube de déploiement (102) et de l'arbre (106) par rapport audit tube d'alimentation (100), ledit embout (60) de dispositif d'étalement étant retenu à l'intérieur dudit tube d'alimentation (100).

14. Applicateur (50) selon la revendication 13, dans lequel lesdits moyens d'arrêt comportent :

un élément de verrouillage (152) situé sur le-dit tube d'alimenentation (100), et une gorge annulaire (174) située sur ledit tube de déploiement (102) adaptée pour venir en prise avec ledit élément de verrouillage (152) dans toute orientation en rotation dudit cube de déploiement (102) par rapport audit tube d'alimentation (100) lorsque ledit embout (60) de dispositif d'étalement est rétracté.

15. Applicateur (50) selon la revendication 1, qui comporte :

une collerette creuse (152) en forme d'entonnoir située au niveau de l'extrémité proximale dudit tube d'alimentation (100) pour guider ledit embout (60) de dispositif d'étalement et le matériau chirurgical dans ledit tube d'alimentation (100).

16. Applicateur (50) selon la revendication 1, dans lequel:

ledit arbre (106) comporte un tube d'irrigation pour alimenter un fluide vers la feuille (65) de matériau chirurgical.

 Applicateur (50) selon la revendication 16, qui comporte :

> une buse (90) située à l'extrémité distale dudit tube d'irrigation pour décharger le fluide à partir de celui-ci.

Applicateur (50) selon la revendication 17, dans lequel:

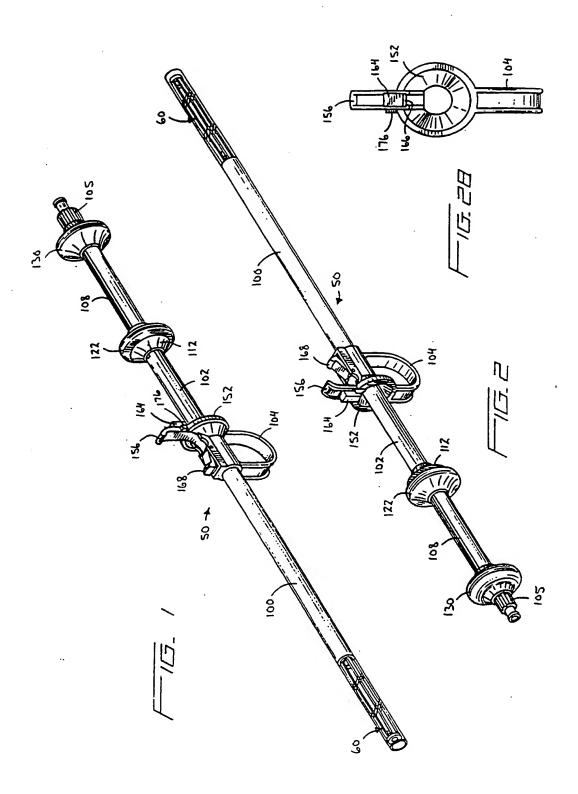
ladite buse (90) comporte plusieurs dents (92) s'étendant distalement destinées à venir en contact avec la feuille (65) de matériau chirurgical pour ajuster le positionnement du matériau chirurgical sur le tissu.

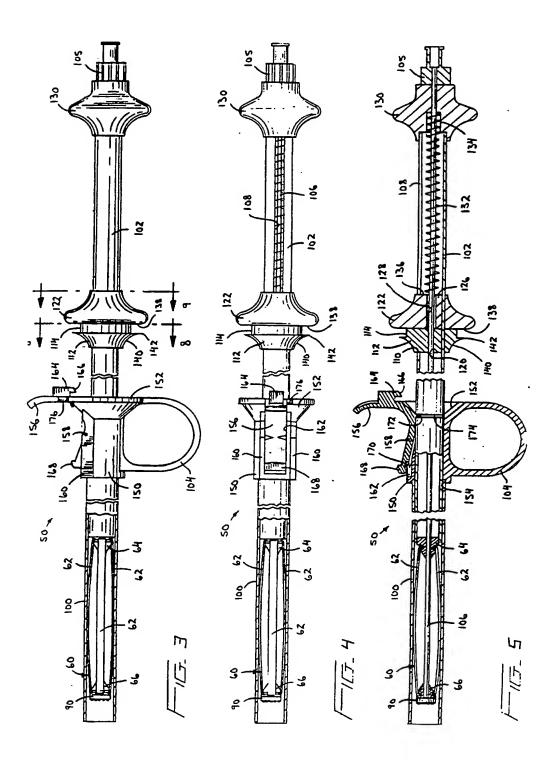
Applicateur (50) selon la revendication 1, qui comporte :

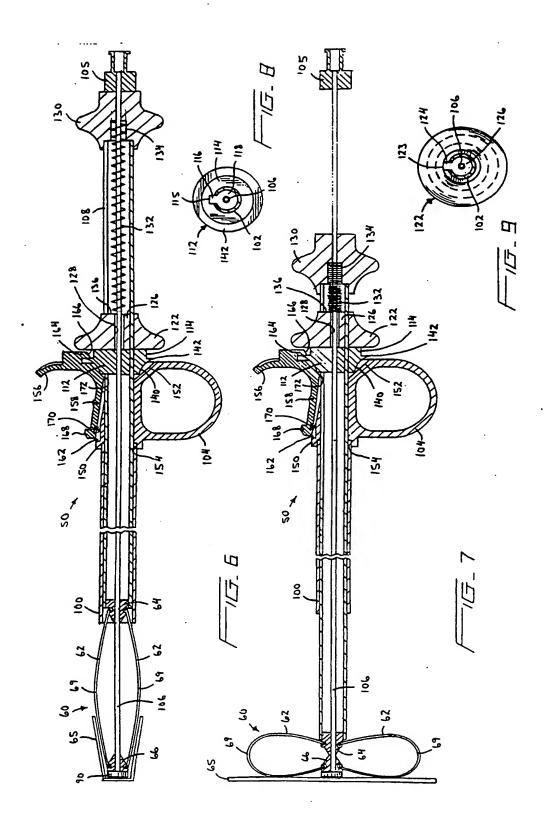
un mécanisme de prise pour fixer la feuille (65) 10 de matériau chirurgical sur ledit embout (60) de dispositif d'étalement.

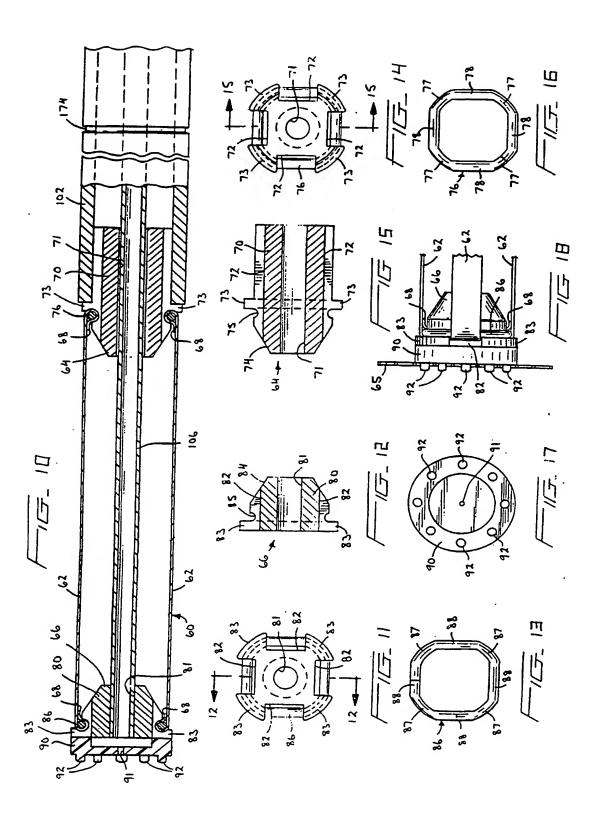
20. Applicateur (50) selon la revendication 19, dans lequel:

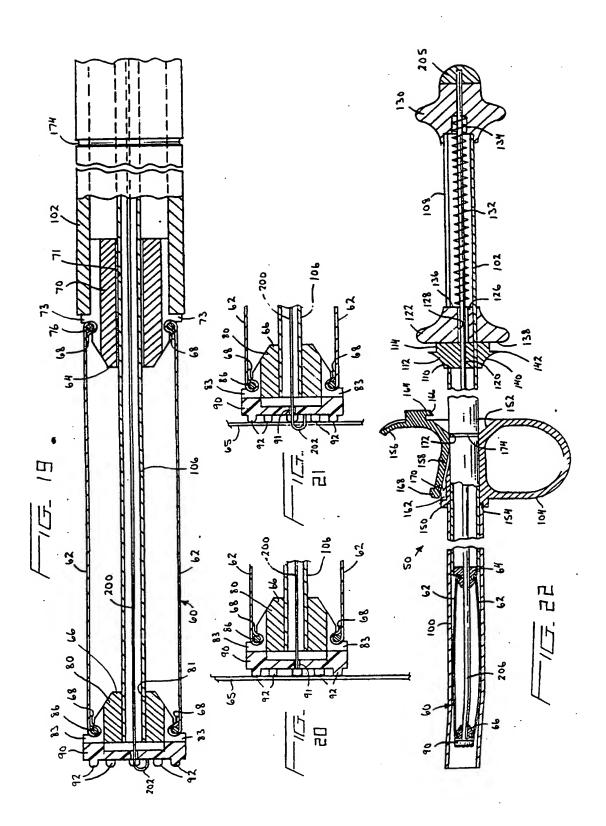
ledit mécanisme de prise comporte un fil (200) monté de manière coulissante sur ledit embout (60) de dispositif d'étalement et muni d'un crochet (202) pour venir en prise avec le matériau chirurgical pour attraper le matériau chirurgical situé sur ledit embout (60) de dispositif d'étalement.

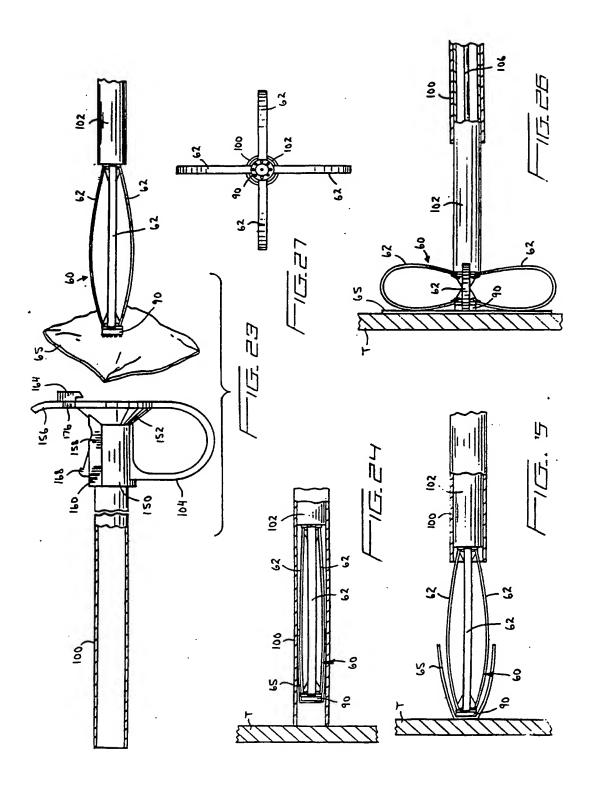












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